3/23/99

K 983229

Section 2 - Summary & Certification

A. 510(k) Summary of Safety and Effectiveness

Classification
Electroencephalograph, 21 CFR 882.1400, Class II, 84GWQ, Neurology

Device Name
Proprietary: Olympic Medical Lectromed Cerebral Function Monitor System
Common Name: EEG Monitor

Company
Olympic Medical
5900 First Ave. S.
Seattle, WA 98108

Contact
Edward B. (Ted) Weiler, Ph.D.
Director of Special Projects
Phone (206) 767-3500; Fax (206) 762-4200

Intended Use
The Olympic Medical Lectromed Cerebral Function Monitor System is intended to monitor the state of the brain by acquisition of EEG signals in the intensive care unit, operating room, and for clinical research.

Predicate Device
Aspect Medical Systems A-2000 EEG Monitor with BIS. (K974496)
SpaceLabs 90482 EEG BIS Module (K973596)

Device Description
The Olympic Medical Lectromed Cerebral Function Monitor System consists of three modules. A header amplifier module is used to connect the patient electrode leads to a plug-in module which produces three outputs which may be monitored or recorded on a 2-channel strip-chart recorder. The three outputs are cerebral function (activity), impedance, and raw EEG.

Safety and Standards
The device meets the following safety standards:

- BS EN 60601-1-1
- BS EN 60601-1-2: 1993 Medical Electrical Equipment
  Part 1. General requirements for safety
  Section 1.2 Collateral Standard for EMC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1999

Edward B. Weiler, Ph.D.
Engineering Manager
Olympic Medical Corporation
5900 First Avenue South
Seattle, Washington 98108

Re: K983229
Trade Name: Olympic Medical Lectromed Cerebral Function Monitor System
Regulatory Class: II
Product Code: GWQ
Dated: December 29, 1998
Received: December 30, 1998

Dear Dr.Weiler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) NUMBER (IF KNOWN): K983229

DEVICE NAME: Olympic Medical Lectromed Cerebral Function Monitor System

INDICATIONS FOR USE:

The Olympic Medical Lectromed Cerebral Function Monitor System is intended to monitor the state of the brain by acquisition of EEG signals in the intensive care unit, operating room, and for clinical research.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983229